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ORIGINAL RESEARCH

TWO YEAR ACL REINJURY RATE OF 2.5%: OUTCOMES REPORT OF THE MEN IN A SECONDARY ACL INJURY PREVENTION PROGRAM (ACL-SPORTS)

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ABSTRACT

Background: The Anterior Cruciate Ligament-Specialized Post-Operative Return to Sports (ACL-SPORTS) randomized control trial (RCT) examined an evidence-based secondary ACL injury prevention training program, involving progressive strengthening, agility training, and plyometrics. The RCT examined the benefit of the training program with and without a neuromuscular training technique called perturbation training.

Hypothesis/Purpose: The purpose of this study was to report the return to sport and second ACL injury incidence outcomes of the men in the ACL-SPORTS trial.

Study Design: Secondary analysis of a RCT

Methods: Forty cutting and pivoting sport male athletes participated in the ACL-SPORTS trial, return to sport testing, and in follow-up sessions at one and two years after ACL reconstruction. Variables of interest at one and two years were return to sport, return to preinjury level of sport, and second ACL injuries. Mean time to passing return to sport criteria, the number of athletes returning to sport and preinjury level of sport and the incidence proportion of second ACL injuries were calculated.

Results: Athletes passed return to sport criteria 232 ± 99 days after ACLR. One year after ACL reconstruction 95% had returned to sport, 78% at their preinjury level. Two years after ACL reconstruction all athletes had returned to sport, 95% at their preinjury level and only one athlete had a second ACL injury.

Conclusions: The results of this study indicate that men in the ACL-SPORTS trial had much higher return to sport rates and much lower second ACL injury rates than those reported in the literature.

Level of Evidence: 1b

Key Words: Anterior cruciate ligament, sport, athletes, return to sport, second injury, rehabilitation

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INTRODUCTION

Before ACL reconstruction, 91% percent of athletes believe they will return to their preinjury levels of sport.¹ After surgery, only 65% actually return to that level.² Athletes who do return to their preinjury levels are at higher risk for a second ACL injury, compared to those who do not return or have no history of ACL injury.³-5 Returning to cutting and pivoting sports increases an athlete's odds for an ipsilateral second ACL injury by 3.9 times and for a contralateral injury by five times.⁵ Such low return to sport and high second ACL injury rates support a need for targeted secondary ACL injury prevention and return to sport programs, however to-date there is a lack of evidence-based programs that report outcomes.

The training program examined in the Anterior Cruciate Ligament-Specialized Post-Operative Return to Sports (ACL-SPORTS) single blinded randomized control trial was developed to be a sport-specific secondary ACL injury prevention program used in the return to sport phase of ACL reconstruction rehabilitation. The training program utilized best practices from the primary ACL injury prevention literature; employing multiple exercise modalities during training, having multiple training sessions per week for a total training duration ≥30 minutes per week, and modeling after primary ACL injury prevention programs shown to be effective in improving landing biomechanics in young female athletes and reducing primary ACL injuries. In

Both groups in the ACL-SPORTS randomized control trial received the training program consisting of progressive strengthening, plyometric, agility, and secondary ACL injury prevention exercises. One group received the training program (SAP group) alone, while the other received the training program with the addition of perturbation training (SAP+PERT group).6,12 Eighty athletes (40 men) participated in the ACL-SPORTS randomized control trial. Enrollment of men proceeded more quickly than women, and all of the men reached the two-year study endpoint before the women. Primary outcomes in the men indicated that at one and two years after ACL reconstruction there were differences between the groups in limb symmetry during three dimensional motion analysis of walking gait.¹³ Further,

there were also no differences between the SAP and SAP+PERT groups in knee function or patient-reported outcomes measures, but both groups had better outcome scores after training than published registry data. These studies indicated that the SAP and SAP+PERT groups could be combined in subsequent secondary analyses, such as this study.

As the training program at the heart of the ACL-SPORTS trial was designed to be a secondary ACL injury prevention program used during the return to sport phase of ACL reconstruction rehabilitation; the purpose of this study was to determine the return to sport, return to preinjury level of sport, and second ACL injury rate of the men who participated in the ACL-SPORTS trial. The authors hypothesized that athletes in the ACL-SPORTS trial would have higher return to sport and lower second ACL injury rates than those published in the literature.

METHODS

The randomized control trial was approved by the University of Delaware Institutional Review Board and registered at clinicaltrials.gov (NCT01773317). Prior to participation, all athletes gave written informed consent (or assent if <18 years old with parent/guardian written informed consent). The methods of the randomized control trial have been published previously. 6 The current study reports on only the men (n = 40) in the original trial. Data collection and analysis of the 40 women in the trial is on-going, and will be published in future work. As this is a publically funded study, the authors feel it is important to inform the public of the trial results as they become available, thus have decided to publish these results as follow-up on the women continues.

The median age of the athletes was 21.5 (range 15-54 years old), and all athletes were regular participants (≥50 hours per year) in Level I (n=38) or II (n=2) ¹⁵ cutting and pivoting type sports prior to their ACL injuries. ⁶ As is typical with most athletes, ¹ all athletes enrolled in the ACL-SPORTS trial intended to return to their preinjury levels of activity. To collect a generalized sample, athletes were recruited from the local community through surgeon and physical therapist referrals, newspaper advertisements, and word of mouth. Athletes were of various skill

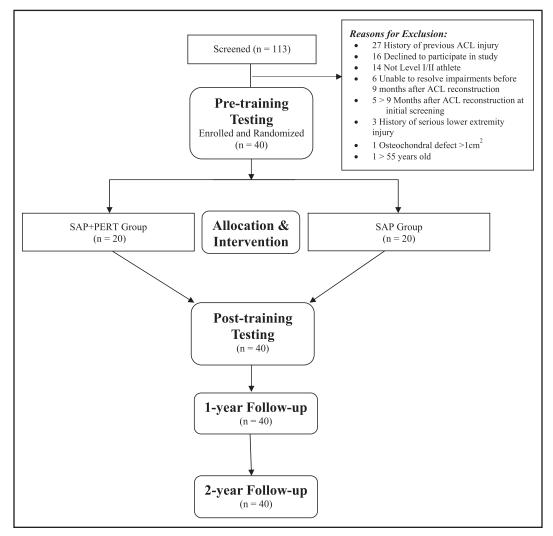


Figure 1. CONSORT flow diagram of athletes through study. As a result of primary outcome studies indicating no difference between athletes who received the training program (SAP) and athletes who received the training program with perturbation training (SAP+PERT), 13,14 particularly in functional measures and patient reported outcomes the groups were collapsed for analysis. 13,14

levels ranging from NCAA Division I (the highest level of university sports in the United States) to youth and adult recreational level. ACL reconstructions were performed by 21 experienced orthopedic surgeons, and post-operative rehabilitation was performed in multiple community physical therapy clinics. Rehabilitation prior to enrollment was not standardized, but enrollment criteria were utilized to ensure a homogenous entry point and athlete safety. Athletes were enrolled at the point where they are typically discharged from physical therapy in the United States; upon achieving activities of daily living goals and beginning to run. Enrollment criteria were: three to nine months after unilateral ACL reconstruction with ≥80% quadriceps strength

limb symmetry (QI), minimal effusion, no pain, full range of motion, and successful completion of a running progression. Athletes were excluded (Figure 1) if they had a concomitant >1 cm² full thickness chondral defect (assessed via arthroscopy or MRI) or grade three ligamentous injury (example medial or lateral collateral ligament), previous ACL reconstruction, a history of major lower extremity injury or surgery to either limb, or had already returned to sport. Only six athletes screened for study were unable to resolve strength, range of motion, effusion, and pain impairments within nine months of their ACL reconstruction indicating these criteria were not too stringent or selective (Figure 1). The primary reason for exclusion from the study were

Group(s)		Sessions 1-3	Sessions 4-6	Sessions 7-10	
Training program (SAP and SAP+PERT) ⁶	Nordic	2x5 (~30-45°)	3x5 (~30-45°)	3x5 (~60°)	
	Hamstrings				
	Standing Squat (Bilateral to 90°)	Session 1: 3x10 focusing on proper technique Session 2 and 3: Add green or blue (per physical therapist discretion) theraband around knees	3x10 progression to black theraband around knees	Not performed	
	Drop Jump	3x10 Taking off and landing bilaterally	3x10 Taking off bilaterally, landing on the involved limb	3x10 Taking off and landing on the involved limb	
		Step height progresses as appropriate for the athlete from 4 to 6 to 8 inches tall	Step height progresses as appropriate for the athlete from 4 to 6 to 8 inches tall	Step height progresses as appropriate for the athlete from 4 to 6 to 8 inches tall	
	Triple Single Leg hopping	Forward/backwards (3 hops forward, 3 hops backwards) x10	Forward/backwards (3 hops forward, 3 hops backwards) x15	Forward/backwards (3 hops forward, 3 hop backwards) x15	
		Side to Side (3 consecutive hops laterally) x10	Side to Side (3 consecutive hops laterally) x15	Side to Side (3 consecutive hops laterally) x15	
		Overground	Over a low object approximately 2 inches high (such as cup or low cone)	Over an object the height appropriate for the patient such as 4 in cones or 6 in hurdles	
	Tuck Jumps	Not performed	Not performed	2 sets for 10-20 seconds Progressing to 3 sets for 20-30 seconds	
SAP Only	Single-leg balance with hip flexor resistance	3 x 30 seconds	3 x 45 seconds	3 x 1 minute	
SAP+PERT Only	Perturbation Training (Appendix A) ^{6,12} Progressed according to athlete response, not by treatment session number -As athlete progresses the speed of perturbations is increased -Perturbations begin in anterior/posterior and medial/lateral and are advanced to include rotation				
	Roller board	Double limb support Single limb support in parallel bars Single limb support out of parallel bars			
	Roller board and stationary platform (one foot on roller board one foot on platform)	Perturbations with feet parallel to each other in a straddle stance Add perturbations with feet in a diagonal stance Add functional task during perturbations			
	Tilt board	Double limb support Single limb support Add functional task during perturbation			

a history of a previous ACL reconstruction (n=27), declining to participate in the study (n=16), and not being a Level I or II athlete (n=14).

The male athletes in the ACL-SPORTS trial were enrolled between November 2011 and June

2014. Upon enrollment, athletes were randomized into either the SAP group $(n=20, Table\ 1)$ or the SAP+PERT group (n=20). Randomization and concealed allocation were performed using a random number generator by a research coordinator (MC) who had no contact with the athletes beyond

scheduling. All researchers performing data collections were blinded to group allocation.

For clarity, the term "training program" was used to refer to the exercises that all athletes performed regardless of group; Nordic hamstring, standing squat, drop jump, triple single-leg hopping, tuck jump exercises and progressive agility drills (Table 1). In accordance with each athlete's sport, the training program was made sport-specific by incorporating movements, such as throwing or kicking, and equipment, such as balls or sticks.6 Training was performed twice a week for five weeks, a total of ten sessions. Sessions were progressed according to soreness and effusion guidelines (Appendix B), 6,16 and supervised by a physical therapist from the University of Delaware Physical Therapy Clinic. Where needed, therapists educated the athletes on correct landing technique and lower extremity alignment during exercises, particularly avoiding knee valgus collapse.

Upon completion of the program all athletes were required to pass return to sports criteria before being cleared to begin to return to sport/activity. These criteria were ≥90% quadriceps strength limb symmetry index (measured isometrically on an electromechanical dynamometer⁶), ≥90% limb symmetry index on four single-legged hop tests (single, crossover, and triple hops for distance and the six meter timed hop tests), 17 and ≥90% scores on the Knee Outcomes Survey-Activities of Daily Living Scale (KOS-ADLS)18 and the global rating of perceived knee function (global rating). These criteria have been used in previous studies,3,19 and achieving ≥90% limb symmetry is not uncommon in the literature. 16,20,21 The number of days from ACL reconstruction to passing the return to sport criteria was recorded. If an athlete did not pass the criteria on the first attempt, a detailed progressive home exercise program was prescribed to address the athlete's deficits and they were retested in approximately one month. Once athletes were cleared to return to sport they were given instructions on how to gradually acclimatize to sport, starting with returning to training without contact, then introducing contact in controlled small groups, progressing to full contact during training sessions and eventually full participation in games.¹⁶

As part of a comprehensive clinical follow-up, one and two years after ACL reconstruction athletes answered the questions "Have you returned to sports or recreational activities?" and "Have you returned to the same level of sports or recreational activities as before your injury?" Athletes also reported if they had sustained a second ACL injury (contralateral or graft rupture). Only two of the 40 men were unable to participate in follow-up sessions in-person but were contacted and answered via telephone.

As previous work examining the primary functional and biomechanical outcomes at one and two years after ACL reconstruction indicated no difference between groups, 13,14 the SAP and SAP + PERT groups were combined for analysis of return to sport and second ACL injury outcomes. Demographic and anthropometric data, such as age, height, weight, mechanism of injury, and graft type were compiled, and mean time to passing the return to sport criteria, return to sport and return to preinjury level of sport rates were calculated. The incidence proportion of second ACL injuries was also calculated by dividing the number of second ACL injuries by the number of men in the ACL-SPORTS study. Means and standard deviations were calculated using Microsoft Excel (Redmond, Washington, USA).

RESULTS

Forty men were enrolled and completed all ten sessions of the training program with no adverse events. (Table 2) The most common sports that subjects participated in were soccer, basketball, American football, lacrosse, ultimate frisbee, flag football, and ice hockey.

Return to sport: The mean time to passing return to sport criteria was 232 \pm 99 days (\sim 7.5 months) after ACL reconstruction. One year after ACL reconstruction all but two (95%) athletes had returned to sport at some level (Table 3). One athlete had not yet passed the return to sport criteria, and the other cited changes in lifestyle/not enough time.

Seven other athletes had not returned to their preinjury level of sport. Three cited fear of reinjury as their reason. Two of the three athletes citing fear had returned to Level III activities (low level jogging and weight lifting) but had not been cleared to return to

Table 2. Demographics and anthropometrics					
Variable					
Age (years)	Mean: 23.3 Median: 21.5 Range: 15-54				
Height (meters)	Mean \pm Standard Deviation: 1.79 ± 0.07				
Weight (kg)	Mean \pm Standard Deviation: 85.39 ± 9.32				
Mechanism of	Contact 18				
Injury	Non-Contact 22				
Graft Type	Allograft: 13 Hamstring Autograft: 19 Bone Patella Tendon Bone Autograft: 8				
Weeks from Surgery to Enrollment	21.5 ± 7.5				

Table 3. Number of athletes who returned to sport and preinjury level of activity at each time point			
	Number of athletes (%)		
1 year			
Return to sport (N=40)	38 (95%)		
Return to Preinjury Level (N=40)	31 (78%)		
2 years			
Return to sport (N=40)	40 (100%)		
Return to Preinjury Level (N=40)	38 (95%)		

their preinjury level as they had not yet passed the return to sport criteria. The other reasons cited for not returning to preinjury level of sport were swelling (1), not enough time (2), and waiting for final clearance from surgeon (1).

At two years all athletes had returned to sport (Table 3), and only two athletes had not returned to their preinjury level. One of these athletes cited not enough time, the other cited fear of reinjury and although he had returned to level III sports, he had not yet passed return to sport criteria.

Second ACL injury: Only one athlete had a second ACL injury. This injury was a graft rupture (allograft) in a 32-year-old. The overall incidence proportion of second ACL injuries was 0.025 injuries/athlete.

DISCUSSION

All athletes in the ACL-SPORTS trial participated in a secondary ACL injury prevention training program designed for use during the return to sport phase of ACL reconstruction rehabilitation. The training program involved ten sessions over five weeks. Each session lasted approximately 60-90 minutes and could be performed in a clinic or on a field/court. As athletes in the United States are typically discharged from physical therapy when they begin basic athletic tasks, such as running; the program was designed to introduce higher-level athletic movements and guide an athlete towards a safe return to sport. The results of the current study indicate that in the first two years after ACL reconstruction all of the men who participated in the ACL-SPORTS trial returned to sport, 95% returned to their preinjury level of sport, and only one experienced a second ACL injury. The findings of this study indicate that the training program may be beneficial for men who wish to safely return to sport after ACL reconstruction.

Return to sport: A 2011 meta-analysis reported that 77% of athletes attempt to return to sport in the first year after ACL reconstruction.²² In the current study, at one year 95% of athletes had returned to sport at some level, and 78% had already returned to their preinjury levels. A 2014 meta-analysis of return to sport rates found that over the five to seven vears after ACL reconstruction 81% of athletes had returned to some level of activity, but only 65% returned to their preinjury level.2 More recently, Failla et al.23 described a cohort similar in demographics and athletic participation to the one in this study, a subgroup of Multicenter Orthopedic Outcomes Network (MOON) cohort. The return to preinjury level of sport rate in that MOON subgroup at two years after ACL reconstruction was 63%. In contrast, by two years after ACL reconstruction 100% of athletes in this study had returned to sport, and 95% had returned to their preinjury level, 37 of 38 to Level I sports.

Studies with return to sport rates as high as those in this study have been published, but are in samples of elite or professional athletes. Waldén et al.²⁴ reported that in elite level soccer 94% of athletes returned to training and 89% returned to match play within one year of their ACL reconstruction. A 2017 meta-analysis found a pooled return to sport rate of 83% for elite athletes, with a 5.3% second ACL injury rate.²⁵ Elite athletes are known to return to play at higher rates than athletes at lower levels² though, potentially because they may receive higher quality or have more frequent access to physical therapy.²⁶ The results of this study demonstrate that high return to sport rates are not limited to elite

level athletes. The cohort in this study had a diverse array of skill levels, ranging from NCAA Division I athletes to high school level players and recreational level adult league participants. Thus, these results suggest that in a general athletic population the rehabilitation involved in the training program may help male athletes return to sport at a higher rate than that reported in the current literature.

Second ACL injury: Second ACL injury rates in young athletes range between 23-36%.5,27-29 The current study found a second ACL injury incidence of 2.5%. No second ACL injuries occurred in the first year after ACL reconstruction, a known high-risk window. 27,30 The only second ACL injury, an ipsilateral allograft injury in a 32-year-old soccer player, occurred late in the second post-operative year. Allografts are known to have a higher risk for graft ruptures compared to autografts.27 Although the injury was non-contact, the athlete attributed the injury to the uneven surface of the soccer field. Following his reinjury, the athlete had no episodes of giving way and met the criteria for non-operative ACL injury treatment.32,33 He returned to his preinjury level of sport within one year of his second ACL injury and remains at this level, non-operatively managed, three years later; suggesting that neuromuscular control was not the primary contributor to this injury. The low rate of second ACL injuries in this study compared to the previous literature indicates that the training program in the ACL-SPORTS trial may be beneficial in secondary ACL injury prevention in men.

There are additional factors beyond the exercise components that could be contributing to the success of the training program. The enrollment criteria ensured that athletes were safe to perform the exercises involved in the training program. Each athlete was required to pass strict return to sport criteria, prior to returning to their preinjury level of sport. Previous authors have shown that passing these return to sport criteria can reduce the risk of reinjury.3 Further, each athlete performed a course of post-operative rehabilitation, followed by the training program, and then were required to pass return to sport criteria. This sequence meant that most athletes passed the return to sport criteria around 7.5 months, likely returning to their preinjury level in the ensuing weeks as they completed their gradual acclimatization. Time delays between ACL reconstruction and return to sport may also have implications for reinjury.³ Future research should examine the implications of each of these factors, but they do not detract from the results of this study. When used together, enrollment criteria, the training program, and strict return to sport criteria produced higher return to sport and lower second ACL injury rates than those available in the published literature.

Strengths and Limitations: This study only examined the outcomes of the 40 men in the randomized control trial. Second ACL injury risk is higher in women than men,^{27,30} and future analyses will examine the results of the women in the ACL-SPORTS randomized control trial. Further prospective studies examining the training program in other, particularly larger, cohorts are needed to discern second ACL injury rates as well as to compare this program to other return to sport programs. This study also relied on athletes' self-report for return to sport and second injury data and did not include exposure data. A strength of this study is its sample. Athletes came from a variety of surgeons and performed their post-operative physical therapy in a number of different community clinics, making the cohort generalizable. The study set reasonable enrollment criteria, to ensure athletes had a standardized entry point into the study, were safe to perform the advanced sport-related tasks but were not selective of only elite or high performing athletes. The generalizability of this cohort, combined with the enrollment criteria, the training program, and the strict return to sport criteria mean that the results of this study have good external validity, and can be implemented clinically.

CONCLUSIONS

In conclusion, all of male athletes enrolled in the ACL-SPORTS trial returned to sport at some level and 95% returned to their preinjury level (39/40, 37/38 to Level I sports) with only one athlete sustaining a second ACL injury in the two years after ACL reconstruction. These results when compared to previous literature demonstrate much higher return to sport and much lower second ACL injury rates. Previous studies have shown that men who participated in the ACL-SPORTS trial had higher knee function

and patient reported outcome measure scores than published registry data one and two years after ACL reconstruction.14 Combined with the results of this study, it seems that the training program examined in the ACL-SPORTS trial may be a beneficial return to sport phase ACL reconstruction rehabilitation intervention for men who wish to safely return to sport.

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Appendix A

Perturbation Training Exercises Bilateral Rollerboard

Unilateral Rollerboard



Unilateral Tiltboard



Appendix B					
Soreness Guidelines (Adams et al ¹⁶)					
If no soreness:	Advance to next session				
If sore during warm-up but soreness is gone during dribbling and juggling warm-up:	Repeat previous session				
If sore during warm-up and soreness continues through dribbling and juggling warm-up:	Stop; take 2 days off, and upon return to training, drop down one session				
If sore more than 1 hour after kicking, or the next day:	Take 1 day off; repeat most recent session				
Effusion Guidelines (Adams et al ¹⁶ and White et al ⁶)					
1+ or less*	Complete protocol and progress as appropriate				
2+ or more*	Hold protocol, treat effusion, and review effusion management				
	At the following session:				
	Trace or None: Progress as appropriate				
	1+: Maintain same level of protocol, do not advance				
	• 2+: Hold protocol, treat effusion, and review effusion management				
	At the next session:				
	• Trace or None: Progress as appropriate				
	• 1+: Progress as appropriate				
	• 2+: Hold protocol, treat effusion, notify research team.				
*Effusion graded according to: Sturgill LP, Snyder-Mackler L, Manal TJ, Axe MJ: Interrater reliability of a clinical scale to assess knee joint effusion. J Orthop Sports Phys Ther. 2009, 39: 845-849.					